

REMARKS

Claims 1, 4, 6-8 and 10-12 are pending. Reconsideration is requested.

Claim 1 stands rejected as being anticipated by Mudambi (Proceed. 26th Conf. Great Lakes Res.). This rejection is traversed for the following reasons.

The device of Mudambi and Hassett was developed to remove extraneous particles from water sample prior to the determination of the organic contaminant Mirex, which was present in picogram quantities. The procedure and principle are completely different from the concept of the present invention, which includes a filtration process within the centrifuge and is concerned with larger particulate matter. The device used by Mudambi and Hassett was, in fact, a milk separating machine made by Alfa-Laval. After passage through the separator, the particle-free water was then passed through a column containing the XAD-8 adsorbent. The process of *adsorption* is different from filtration. The molecules of the contaminant are adsorbed to the surface of the matrix (XAD-8) and removed from the water. Subsequently, these molecules are eluted from the matrix and passed through a complex analytical apparatus. The device of the present invention, combines the filtration column in the centrifuge, so concentration and filtration occurs simultaneously and the particles trapped in the filter can be eluted and examined microscopically after the main filtration process. This allows for great economy of time and material.

Claims 1, 4, 6-8 and 10-13 have been rejected as being obvious over Whitmore (Wat. Sci. Tech. 1993) in view of U.S. Pat. No. 5,019,497. This rejection is traversed for the following reasons.

Whitmore and Carrington compare a variety of methods for the removal and identification of *Cryptosporidium* oocysts. They clearly state in the abstract that the Membrex standard method of removing *Cryptosporidium* oocysts consisted of passing large volumes of water through cartridge filters, but this was tedious and recoveries were only of the order of 30-40%. They tried a continuous centrifuge with very low recovery because they did NOT incorporate the filter within the centrifuge itself, as does the present invention, and achieved a very poor recovery compared with the present

invention. It is respectfully submitted that there is no teaching or suggestion in Whitmore and Carrington to incorporate the filter within the centrifuge, as in the present invention. Whitmore and Carrington experimented with several other systems and showed the value of cross-flow filtration. This technique is complex and expensive to operate. In contrast, the device and method of the present invention is simple and inexpensive, and does not resemble the system of Whitmore and Carrington.

With respect to claims 11 and 12, the Examiner has taken the position that the cited references make the claimed invention obvious, and that the choice of sizes of the particulate material is a matter of routine experimentation. For the reasons given above, it is respectfully submitted that the cited references do not teach or suggest the invention as broadly claimed, and that consequently no amount of routine experimentation would yield the invention as claimed in claims 11 and 12. Reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner appears to take the position in paragraph 8 of the Office Action that adsorption is the same as filtration. Applicants strongly disagree. Adsorption is the adhesion of an extremely thin layer of molecules to the surfaces of solid bodies or liquids with which they are in contact. This process is not applicable to the present invention.

For these reasons, it is respectfully submitted that claims 1, 4, 6-8 and 10-12 are not obvious from the combination of Whitmore and Carrington. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 4, 6-8 and 10-12 have been rejected as being obvious over Borschardt (U.S. Pat. No. 5,846,439) in view of Leu (U.S. Pat. No. 5,866,071). This rejection is traversed for the following reasons.

Borchardt teaches the use of a continuous separation channel centrifuge, as depicted in Figure 1 of U.S. Pat. No. 5,846,439. The centrifuge used in the methods of the present invention is completely different, as shown in Figure 1 of the present application. In the method taught by Borchardt, collected parasites are retained in the channel labelled "12" in Figure 1. In Applicants' invention, parasites are collected in replaceable sample tubes. It is respectfully submitted that a filtration column of particulate material, as employed in the present invention, cannot be added to a channel

as taught by Borchardt. Furthermore, in the method disclosed by Borchardt, the collected material must be removed from the separation channel before a subsequent sample can be processed. In Applicants' claimed method, the sample collection tubes need merely be replaced.

Applicants also respectfully submit that the centrifuge apparatus used by Borchardt is far more complex than that of the present invention, and will not be operable for the purposes of the present invention. Any apparatus used for these purposes must perform with natural water with various quantities of sediment. A delicate piece of apparatus designed for medical work, as used by Borchardt, that was designed to centrifuge a few liters of blood, cannot handle quantities of up to 20-30 liters of water.

It is also submitted that the Borchardt reference "teaches away" from the present invention. For example, at column 2, lines 28-29, it is stated that "the sand column system was judged inadequate for monitoring because of poor retention of oocysts...".

The Leu patent does not remedy the deficiency of the Borchardt patent to suggest the present invention. First, there is no suggestion in either Borchardt or Leu that would motivate a person skilled in the art to combine the two documents. The Borchardt patent is directed to the use of a continuous separation channel centrifuge, whereas the Leu patent is directed to a centrifuge tube to be used for separation after density gradient centrifugation. These two processes are inherently different. Furthermore, there does not appear to be any way that the centrifuge tube of Leu can be combined with Borchardt to yield the present invention. In addition, the centrifuge tube of Leu is designed for removal of gradients following density gradient centrifugation, and not for operation during the centrifugation process itself. It is respectfully submitted that even were the teachings of these two patents able to be combined, it would not result in the present invention. Finally, as noted above, Borchardt teaches away from the use of a sand column system, and makes no mention of glass beads. Thus, the suggestion to use the required element of a filtration column of particulate material is missing from the teachings of these documents.

The Examiner states that "in the apparatus of Leu, a column is packed with finely divided dextran particles (column 4, lines 35-53)". No mention can be found of particles

at that location, nor any other location in the Leu patent. The passage cited by the Examiner refers to dextran solutions of varying concentrations. These solutions cannot be considered to be comparable to the glass beads or particulate matter of graded sizes of the present invention.

In addition, Borchardt and Leu both deal with small quantities of fluid and in the examples demonstrated by the work of Contant-Poussard et al. (2000) deal with highly sophisticated laboratory methods to separate microorganisms that are one tenth to one one hundredth the size of *C. parvum* oocysts. Although all of the techniques use filtration techniques of one sort or another, the discussion dealing with molecular sieves and atomic separation is completely irrelevant. Applicants do not dispute that there are numerous ways to filter particles, and even color filters to separate particles of light (photons). However, the cited references deal with small volumes of liquid, at most 5-10 ml, whereas the apparatus of the invention can process, centrifuge and filter 25-50 liters of water in 20-30 minutes at a cost of pennies. The difference in price between Sephadex and the glass particles is enormous. 100 gm of sephadex or dextran costs approximately \$30-50, the same cost as 50 kilograms of the material used in the apparatus of the present invention.

For all of the above reasons, it is respectfully submitted that claim 1 is not obvious from the combination of Borchardt and Leu. Reconsideration and withdrawal of the rejection is respectfully requested.

With respect to claims 4 and 12, it is the Examiner's position that Borchardt combined with Leu teaches the claimed invention as stated above, except for the use of glass or sand particulate material, and that Borchardt discloses that it is known in the art to use sand columns to filter oocysts from water in flow systems. According to the Examiner's position, it would be obvious to use sand columns in the centrifuge of Borchardt in replacement of the media of Leu, as sand columns are known to filter oocysts.

Applicants respectfully disagree. As discussed above, Borchardt teaches away from the use of sand columns, and makes no mention of glass beads. Thus, it would not have been obvious to a person of skill in the art to make such a combination. For this

reason, as well as those discussed above, it is respectfully submitted that claims 4 and 12 are not obvious from Borchardt in combination with Leu. Reconsideration and withdrawal of the rejection are respectfully requested.

With respect to method claims 6-8, it is the Examiner's position that Borchardt teaches that it is known in the art to perform microorganism concentration in a fluid stream of a continuous flow centrifuge. However, the combination of Borchardt and Leu fails to disclose an apparatus that is capable of concentrating microorganisms from large volumes of fluid, as is the presently claimed apparatus. Any apparatus used for these purposes must perform with natural water with various quantities of sediment. A delicate piece of apparatus designed to centrifuge a few liters of blood cannot handle quantities up to 20-30 liters of water. For this reason, it is respectfully submitted that any apparatus resulting from the combination of Borchardt with Leu would not be able to carry out the method of the invention as claimed in claims 6-8. Reconsideration and withdrawal of the rejection is respectfully requested.

With respect to claims 11-12, it is the Examiner's position that the combination of Borchard with Leu yields the claimed invention except for the claimed size ranges for the beads or sand, which are considered to be a matter of routine experimentation.

Appellants respectfully submit that, for the reasons presented above, Borchardt combined with Leu does not result in the present invention as broadly claimed, and that therefore no amount of routine experimentation would result in the invention as claimed in claims 11-12. Reconsideration and withdrawal of the rejection is respectfully requested.

For all of the above reasons, it is respectfully submitted that the pending claims are neither anticipated by nor obvious in view of the cited references. Reconsideration and withdrawal of the 35 USC §102 and 35 USC §103 rejections are respectfully requested.

Finally, it is noted that the Examiner believes Applicants' representative has "acquiesced" to the Examiner's assertion that the dextran column taught by Leu is a filtration medium (paragraph 9 of the Action). No such statement can be found on page 2 of the March 4, 2003 response, to which the Examiner refers. Clarification is requested.

All rejections having been addressed, it is respectfully submitted that this application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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